

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
**(Under 37 CFR 1.97(b) or 1.97(c))**

Docket No.  
015/03937

In Re Application Of: **Tami HAREL et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/804,560	March 18, 2004	Unknown	44909	3762	7075

Title: **BLOOD GLUCOSE LEVEL CONTROL**



Address to:  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

**OR**

☐ the fee set forth in 37 CFR 1.17(p).

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
015/03937

In Re Application: **Tami HAREL et al.**

Application No. 10/804,560	Filing Date March 18, 2004	Examiner Unknown	Customer No. 44909	Group Art Unit 3762	Confirmation No. 7075
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**BLOOD GLUCOSE LEVEL CONTROL**



**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **03-3419** as described below.
- ☐ Charge the amount of \_\_\_\_\_
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.

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I certify that this document and fee is being deposited on \_\_\_\_\_ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**\*This certificate may only be used if paying by deposit account.**

Dated: **July 28, 2004**

Signature

**Maier FENSTER, Reg. No. 41,016**

**William H. Dippert, Esq.  
Reed Smith LLP  
599 Lexington Avenue, 29th Floor  
New York, NY 10022-7650**

**Tel: (212) 521-5400**

cc:



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In regard to the application of: Tami HAREL et al.

Serial No : 10/804,560

Group Art Unit: 3762

Filed : March 18, 2004

Examiner: Unknown

For : Blood Glucose Level Control

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Hon. Commissioner of Patents and Trademarks  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants respectfully direct the attention of the Examiner to art cited with respect to U.S. Application No. 10/804,560, which is a continuation-in-part under 35 U.S.C. §111(a) of PCT Application No. PCT/IL03/00736, which is a continuation-in-part under 35 U.S.C. §111(a) of U.S. Application No. 10/237,263, which is a continuation-in-part under 35 U.S.C. §111(a) of PCT Application No. PCT/IL00/00566. This application is also a continuation-in-part under 35 U.S.C. §111(a) of PCT Application No. PCT/IL00/00132, now U.S. Application No. 09/914,889. This application claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Application No. 60/123,532 and U.S. Provisional Application No. 60/488,964.

The Examiner is respectfully requested to review and consider this art, in accordance with MPEP §2001.06, MPEP §1893.03(e) and MPEP §1893.03(g) and to indicate in the first office action that he has considered this art. Additionally, the Examiner is respectfully requested to cite those prior art publications mentioned in this application which the Examiner considers to be material or relevant to the present claims.

Further, in order to comply with discretionary regulations 37 C.F.R. §1.97 and §1.98, attached is an Equivalent to Form PTO-1449 listing the cited art. Also attached are copies<sup>1</sup> of the art. This art contains information which the Examiner may consider to be important in deciding whether to allow the present application to issue as a patent.

Applicants wish to point out that items 2, 9-11, 13, 16, 19, 22, 29-38, 43-54, 56-60, and 62-70 were cited in the parent U.S. Application No. 10/237,263. Copies of these items are not attached as they are available in the parent case.

Applicants further wish to point out that items 1, 3-8, 12, 14, 15, 17, 18, 20, 21, and 23-28 are not attached, as the USPTO waived the requirement under 37 C.F.R. §1.98(a)(2)(i) for submitting copies of U.S. patents and U.S. patent application publications in all U.S. applications filed after June 30, 2003. See OG Notice published on August 5, 2003.

In accordance with MPEP §609 it is requested that each document cited (including any mentioned in Applicants' specification which is not repeated on the attached PTO-1449 form or equivalent thereof) be given thorough consideration and be cited of record in the prosecution history of the present application by initialing on the PTO-1449 form or its equivalent, so that it will appear on the face of the patent issuing on the present application, even if the Examiner does not consider it sufficiently pertinent to use in a rejection, or otherwise does not believe that the guidelines for citation have been fully complied with.

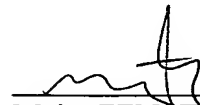
The present Information Disclosure Statement is being submitted in compliance with 37 C.F.R. §1.56 as an Examiner might consider any cited document important in deciding whether to allow the application to issue as a patent, but the citation of each document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 C.F.R. §1.104(a), and in the course of such search will review for relevance every document cited on the attached form.

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<sup>1</sup> To the extent that a document is listed and no copy of same is attached, then such document is not at the present time available to the undersigned or is available in the parent file. If a listed document is not in the English language and an English translation is readily available, such translation is also attached; if translation is not attached, it is not readily available to the undersigned. If a foreign language patent document is cited, and an English language equivalent is known to the undersigned, then such an equivalent patent is also cited on the attached form along with the corresponding foreign language patent and a connecting arrow indicated therebetween; if no such English language equivalent is cited then none is known to the undersigned.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,  
Tami HAREL et al.



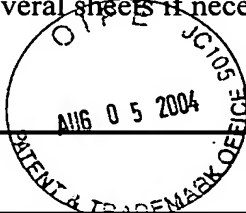
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<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)	ATTY DOCKET NO. <b>015/03937</b>	SERIAL NO. <b>10/804,560</b>
	APPLICANT(S) <b>Tami HAREL et al.</b>	
	FILING <b>March 18, 2004</b>	GROUP <b>3762</b>



### U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	Filing date if appropriate
	1	3,796,221	12 Mar '74	HAGFORS, N. R.			
	2	4,428,366	31 Jan '84	FINDL, E. et al.			
	3	5,031,617	16 Jul '91	KLETTNER, H. L.			
	4	5,101,814	7 Apr '92	PALTI, Y.			
	5	5,190,141	2 Mar '93	PALTI, Y.			
	6	5,231,988	3 Aug '93	WERNICKE, J. F. et al.			
	7	5,540,734	30 Jul '96	ZABARA, J.			
	8	5,561,165	1 Oct '96	LAUTT, W. W. et al.			
	9	5,741,791	21 Apr '98	OLSEN, U. B.			
	10	5,919,216	6 Jul '99	HOUBEN, R. P. M. et al.			
	11	5,995,872	30 Nov '99	BOURGEOIS, I.			
	12	6,066,163	23 May '00	JOHN, M. S.			
	13	6,093,167	25 Jul '00	HOUBEN, R. P. M. et al.			
	14	6,135,978	24 Oct '00	HOUBEN, R. P. M. et al.			
	15	6,261,280	17 Jul '01	HOUBEN, R. P. M. et al.			
	16	6,292,693	18 Sep '01	DARVISH, N. et al.			
	17	6,298,254	2 Oct '01	TAMADA, J.			
	18	6,558,345	6 May '03	HOUBEN, R. P. M. et al.			
	19	6,571,127	27 May '03	BEN-HAIM, S. et al.			
	20	6,572,542	3 Jun '03	HOUBEN, R. P. M. et al.			
	21	6,600,953	29 Jul '03	FLESLER, M. et al.			
	22	6,612,983	2 Sep '03	MARCHAL, B.			
	23	6,630,123	7 Oct '03	WOLTERING, E. A. et al.			

### U.S. PATENT APPLICATION PUBLICATIONS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	Filing date if appropriate
	24	2002/0026141	28 Feb '02	HOUBEN, R. P. M. et al.			
	25	2002/0081732	27 Jun '02	BOWLIN, G. L. et al.			
	26	2003/0055464	20 Mar '03	DARVISH, N. et al.			
	27	2003/0208242	6 Nov '03	HAREL, T. et al.			

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### U.S. PATENT APPLICATION PUBLICATIONS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	Filing date if appropriate
	28	2004/0059393	25 Mar '04	POLICKER, S. et al.			

### FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
	29	GB 1 394 171	14 May '75	UNITED KINGDOM				
	30	WO 93/02743	18 Feb '93	PCT				
	31	WO 97/15227	1 May '97	PCT				
	32	WO 97/25098	17 Jul '97	PCT				
	33	WO 97/27900	7 Aug '97	PCT			✓	
	34	WO 98/10831	19 Mar '98	PCT				
	35	WO 98/10832	19 Mar '98	PCT				
	36	WO 98/56378	17 Dec '98	PCT				
	37	WO 98/57701	23 Dec '98	PCT				
	38	WO 99/03533	28 Jan '99	PCT				
	39	WO 01/91854	6 Dec '01	PCT				
	40	WO 02/053093	11 Jul '02	PCT				
	41	WO 02/082968	24 Oct '02	PCT				
	42	WO 03/045493	5 Jun '03	PCT				

### OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, Etc.)

	43	ADHEGATE, E. et al.; "Effect of Electrical Field Stimulation on Insulin and Glucagon Secretion from the Pancreas of Normal and Diabetic Rats;" Horm Metab Res 2001; Vol. 33; Pages 281-289
	44	BERGSTEN, P. et al.; "Synchronous Oscillations of Cytoplasmic Ca <sup>2+</sup> and Insulin Release in Glucose-Stimulated Pancreatic Islets;" March 1994; The Journal of Biological Chemistry; Vol. 269; No. 12; Pages 8749-8753
	45	Best and Taylor's Physiological Basis of Medical Practice; edited by WEST, J. B.; 12th Edition; Chapter 50; "The Endocrine Pancreas;" Pages 754-769; Williams & Wilkins

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**OTHER DOCUMENTS** (Including Author, Title, Date Pertinent Pages, Etc.)

	46	BOUAZIZ, A. et al.; "Direct Electrical Stimulation of Insulin Secretion by Intact Murine Islets of Langerhans Through the Culture Support;" 1998; Electro- and Magnetobiology; Vol. 17; No. 2; Pages 171-184
	47	DAVIS, S. N. et al.; "Insulin, Oral Hypoglycemic Agents, and the Pharmacology of the Endocrine Pancreas;" The Pharmacological Basis of Therapeutics; Chapter 60; pages 1487-1499; Pages 1507-1510
	48	GOLD, G. et al.; "Evidence that Glucose "Marks" $\beta$ Cells Resulting in Preferential Release of Newly Synthesized Insulin; October 1, 1982; Science; Vol. 218; Pages 56-58
	49	HINKE, S. A. et al.; "Dipeptidyl Peptidase IV (DPIV/CD26) Degradation of Glucagon, Characterization of Glucagon Degradation Products and DPIV-Resistant Analogs;" February 11, 2000; The Journal of Biological Chemistry 2000; Vol. 275; No. 6; Pages 3827-3834
	50	HOLST, J. J. et al.; "Nervous Control of Pancreatic Endocrine Secretion in Pigs;" January 1981; Acta Physiologica Scandinavica; Vol. 111; Pages 1-7; XP000980527
	51	HOLST, J. J. et al.; "Nervous Control of Pancreatic Endocrine Secretion in Pigs;" January 1981; Acta Physiologica Scandinavica; Vol. 111; Pages 9-14; XP000980528
	52	KUFFLER, S. W. et al.; "Release of Chemical Transmitters;" Chapter 10; Pages 241-261; From Neuron to Brain, a Cellular Approach to the Function of the Nervous System; Second Edition; Sinauer Associates Inc. Publishers; Sunderland, Massachusetts
	53	KUROSE, T. et al.; "Glucagon, Insulin and Somatostatin Secretion in Response to Sympathetic Neural Activation in Streptozotocin-Induced Diabetic Rats. A Study with the Isolated Perfused Rat Pancreas In Vitro;" 1992; Diabetologia; Vol. 35; Pages 1035-1041
	54	LIU, S. et al.; "2-Pyridylthioureas: Novel Nonpeptide Somatostatin Agonists with SST <sub>4</sub> Selectivity;" April 1999; Current Pharmaceutical Design; Vol. 5; No. 4; Pages 255-263
	55	LUIKEN, J. J. et al.; "Contraction-Induced Fatty Acid Translocase/CD36 Translocation in Rat Cardiac Myocytes Is Mediated Through AMP-Activated Protein Kinase Signaling;" July 2003; Diabetes; Vol. 52, No. 7; Pages 1627-1634; Department of Physiology, Cardiovascular Research Institute Maastricht; Maastricht University; the Netherlands and Department of Kinesiology; University of Waterloo; Waterloo; Canada

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**OTHER DOCUMENTS** (Including Author, Title, Date Pertinent Pages, Etc.)

	56	MEURER, J. A. et al.; "Properties of Native and In Vitro Glycosylated Forms of the Glucagon-Like Peptide-1 Receptor Antagonist Exendin (9-39);" June 1999; Metabolism; Vol. 48; No. 6; Pages 716-724
	57	MISLER, S. et al.; "Electrophysiology of Stimulus-Secretion Coupling in Human $\beta$ -Cells;" October 1992; Diabetes; Vol. 41; Pages 1221-1228
	58	OHINATA, K. et al.; "Proadrenomedullin N-Terminal 20 Peptide (PAMP) Elevates Blood Glucose Levels Via Bombesin Receptor in Mice;" 12 May 2000; FEBS Letters; Vol. 473; No. 2; Pages 207-211
	59	PALTI, Y. et al.; "Islets of Langerhans Generate Wavelike Electric Activity Modulated by Glucose Concentration;" May 1996; Diabetes; Vol. 45; pages 595-601
	60	PARK, H. S. et al.; "Significant Cholinergic Role in Secretin-Stimulated Exocrine Secretion in Isolated Rat Pancreas;" February 1998; American Journal of Physiology; Vol. 274; No. 2; Pt. 1; Pages G413-G418; XP002157834
	61	PORKSEN, N. et al.; "Pulsatile Insulin Secretion: Detection, Regulation, and Role in Diabetes;" February 2002; Department of Endocrinology and Metabolism M, Aarhus University Hospital; Aarhus; Denmark; Diabetes; Vol. 51; Supplement 1; Section 6: "Pulsatile and Phasic Insulin Release in Normal and Diabetic Men;" Pages S245-S254
	62	RIVERA, V. M. et al.; "Regulation of Protein Secretion Through Controlled Aggregation in the Endoplasmic Reticulum;" February 4, 2000; Pages 826-830
	63	SCHIRRA, J. et al.; "Exendin(9-39)amide Is an Antagonist of Glucagon-Like Peptide-1(7-36)amide in Humans;" April 1, 1998; Journal of Clinical Investigation; Vol. 101; No. 7; Pages 1421-1430
	64	SERRE, V. et al.; "Exendin-(9-39) Is an Inverse Agonist of the Murine Glucagon-Like Peptide-1 Receptor: Implications for Basal Intracellular Cyclic Adenosine 3',5'-Monophosphate Levels and B-Cell Glucose Competence;" November 1998; Endocrinology; Vol. 139; No. 11; Pages 4448-4454
	65	SHAH, P. et al.; "Impact of Lack of Suppression of Glucagon on Glucose Tolerance in Humans; August 1999; American Journal of Physiology; Vol. 277 (2 pt 1); Pages E283-E290

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**OTHER DOCUMENTS** (Including Author, Title, Date Pertinent Pages, Etc.)

	66	SINGH, J. et al.; "Effects of Islet Hormones on Nerve-Mediated and Acetylcholine-Evoked Secretory Responses in the Isolated Pancreas of Normal and Diabetic Rats;" March 1998; International Journal of Molecular Medicine; Vol. 1; No. 3; Pages 627-634; XP000980499
	67	VALDEOLMILLOS, M. et al.; "In-Vivo $\beta$ -Cell Synchronous Oscillations;" 1996; Journal of Physiology; Vol. 493; No. 1; Pages 10-18
	68	WANG, F. et al.; "Islet Amyloid Polypeptide Tonally Inhibits $\beta$ -, $\alpha$ -, and $\delta$ -Cell Secretion in Isolated Rat Pancreatic Islets;" January 1999; American Journal of Physiology; Vol. 276 (1 pt 1); Pages E19-E24
	69	WRIGHT, L. M. et al.; "Structure of Fab hGR-2 F6, a Competitive Antagonist of the Glucagon Receptor;" May 2000; Acta Crystallographica Section D Biological Crystallography; Vol. 56 (pt 1); Pages 573-580
	70	YONEMURA, Y. et al.; "Amelioration of Diabetes Mellitus in Partially Depancreatized Rats by Poly(ADP-Ribose) Synthetase Inhibitors. Evidence of Islet B-Cell Regeneration;" April 1984; Diabetes; Vol. 33; No. 4; Pages 401-404

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